REMARKS/ARGUMENTS

With this amendment, claims 1 and 5-9 are pending. For convenience, the Examiner's rejections are addressed in the order presented in the October 29, 2003, Office Action. Applicants thank Examiner Ford and her supervisor Examiner Smith for their time in allowing an interview with Applicant's representatives Beth Kelly and Joe Snyder on February 3, 2004. The arguments to overcome the rejection under 35 U.S.C. §103(a) were discussed, but no agreement was reached.

I. Status of the claims

Claim 1 is amended to recite that the IgG4 immunoglobulin has a decreased risk of aggregating and fragmenting when manufactured using the claimed methods. Support for this amendment is found throughout the specification, for example at page 2, lines 16-21. This amendment is not a limiting amendment and adds no new matter.

II. Rejections under 35 U.S.C. §103(a)

A. Introduction

Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Laursen *et al.* (U.S. Patent No. 6,281,336) in view of Flaa *et al.* (U.S. Patent 6,165,336). In response, Applicants respectfully traverse the rejection.

Laursen *et al.* disclose methods of purifying a total IgG preparation from plasma. Laursen *et al.* disclose that the purpose of the IgG preparation is in treating patients with disease or conditions that benefit from replacement or supplementation of the total IgG component of blood, including *e.g.*, primary and secondary agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiency, treatment of autoimmune diseases, treatment of certain patients with immune conditions. See, *e.g.*, Laursen *et al.* at column 15, lines 8-47. Laursen *et al.* first adjust the pH of plasma to a pH lower than 6.0, *e.g.*, preferable pH 5.4. See, *e.g.*, Laursen *et al.*, at column 5, lines 12-17. After additional steps, including elution from anion and cation exchange resins, Laursen *et al.* arrive at their disclosed product, a total IgG preparation

which **requires** subtype distribution close to that of blood. See, *e.g.*, Laursen *et al.*, column 20, lines 9-15. Laursen *et al.* disclose the IgG subclass distribution in their total IgG product and in commercially available total IgG products in percentage form in a Table at columns 17 and 18. The percent IgG4 in these products ranges from 0.6% to 1.5% and is described as being within the subclass distribution range of blood. Flaa *et al.* teach solutions for stabilizing proteins, which, in some embodiments, include sugars such as lactose, as bulking agents.

In contrast, the claimed invention is a method of manufacturing purified *IgG4 immunoglobulin subtype*, free of IgG1, IgG2 and IgG3 subtypes for the treatment of allergic reactions, including serious insect sting allergies. As a first step, the pH of plasma is adjusted to a value of about 6.5. The plasma is then subjected to anion exchange chromatography, followed by cation exchange chromatography to obtain an IgG4 preparation that is essentially free of other IgG subtypes.

In order to establish a *prima facie* case of obviousness the Office Action must demonstrate that the cited references provide a suggestion or motivation for their modification or combination, a reasonable expectation of success in the combination, and that the references teach or suggest all the claim limitations. All three elements set forth above must be present in order to establish a *prima facie* case of obviousness. Applicants assert that a *prima facie* case of obviousness has not been established for the following reasons: 1) there is no suggestion or motivation to modify the references; 2) there is no reasonable expectation of success; and 3) the cited art references do not teach or suggest all the claim limitations.

Particular care must be taken to avoid use of hindsight in obviousness analysis. According to 35 U.S.C. §103(a), a claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." The phrase "at the time the invention was made" ensures that obviousness analysis is performed without the benefit of impermissible hindsight. The Federal Circuit has ruled that

> . . . the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. . . . Combining prior art references without evidence

> of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (1999), citations omitted.

The Federal Circuit recognizes that evidence of a suggestion, teaching or motivation to combine can be found in a number of sources. However, actual evidence of a suggestion, or teaching, or motivation to combine is required and the showing of a suggestion, or teaching, or motivation to combine must be "clear and particular." *Id.*

As discussed below the cited references fail to support a prima facie case of obviousness. None of the cited references provide the required clear and particular evidence of a suggestion, teaching, or motivation for their combination. In addition, the cited references, alone or in combination, fail to provide all the elements of the claimed invention.

B. The cited art does not teach or suggest all the elements of the claimed invention.

Laursen *et al.* teaches use of different method steps then the steps recited in the claims. Laursen *et al.* also arrive a different end product then the purified IgG4 recited in the claims. Flaa *et al* is silent as to stabilization of immunoglobulin proteins.

1. The cited art uses different method steps.

The cited art teaches, as a first step, adjusting the pH of a plasma protein containing fraction to a pH below 6, preferably 5.4. (See *e.g.*, Lausen *et al.* at column 5, lines 9-17.) In contrast, the claims recite as a first step adjusting the pH of plasma to about 6.5. Clearly, a pH of 6.5 is greater than the maximum pH 6 recited by Laursen *et al.*, and thus the method of Laursen is not encompassed by the claims.

Laursen *et al.* also teach away from use of pH values greater than six, as used in the claimed methods. Laursen *et al.* state that a pH below 6.0 is required to solubilize the total IgG proteins in a subsequent PEG precipitation step. Therefore, Laursen *et al.* teach away from use of pH values greater than 6, *e.g.* the claimed 6.5 pH value. Lacking the claimed adjustment of plasma pH to a value of 6.5, Laursen *et al.* fail to teach all the steps of the claimed method.

2. The cited art teaches manufacture of a different product.

Laursen *et al.* teach manufacture of an IgG preparation with 1.5% IgG4 subtype, *i.e.*, 98.5% of the IgG molecules are subtypes IgG1, IgG2, or IgG3. The present claims recite as a final product, a cationic effluent comprising IgG4 that is essentially free of other IgG subtypes. In the telephone interview, Examiners Ford and Smith speculated that other IgG subtypes are present in the final products in amounts similar to those disclosed in Laursen *et al.* Applicants assert, first, that the meaning of essentially free of other IgG subtypes is clear on its face to those of skill and refers to a product that has very high levels of IgG4 relative to other IgG subtypes, *e.g.*, at least 95% IgG4. Second, the specification provides a measure of the amount of IgG4 subtype in the final product at page 7, lines 26-27. "[The cation] effluent is mostly, if not entirely, IgG4." Third, evidence of the composition of the final IgG4 product has been provided to the Examiner in a declaration from inventor William Pollack, submitted January 31, 2002. (Resubmitted as Exhibit A.) At page 3, paragraph 7, Dr. Pollack states that the product of the claimed method is "an IgG4 preparation free of other subtypes." While the claims are not rejected under 35 U.S.C. §112, second paragraph, Applicants respectfully assert that the meaning of " IgG4 essentially free of other IgG subtypes" is clear to those of skill and does not encompass the product disclosed in Laursen *et al.* Thus, the product of the claimed methods is not disclosed in Laursen *et al.*, or in any other reference cited in the Office Action.

The Office Action also appears to assert that a table in Laursen *et al.* at columns 17 and 18 discloses a purified IgG4 preparation. This interpretation is incorrect. Laursen *et al.* characterize the IgG subclass distribution in their total IgG product and in commercially available total IgG products in percentage form in the table at columns 17 and 18. The percent IgG4 in these products ranges from 0.6% to 1.5% and is described as being within the subclass distribution range of blood. Applicants respectfully assert that the disclosure that 1.5% of the IgG in the Laursen *et al.* product is IgG4 does not mean that IgG4 has been purified away from other IgG molecules. IgG subclass distribution reported in the table was determined using immunodiffusion assays (see, *e.g.*, Laursen *et al.* at column 20, lines 6-8) which rely on binding of additional immunoglobulins to the IgG4 molecules for detection. Thus, even if the

characterization of the amount of IgG4 by immunodiffusion could somehow be construed to be a purification step, the IgG4 detected in the immunodiffusion assay is not essentially free of other IgG subtypes as maintained by the Office Action.

Because neither the product of Laursen *et al.*, nor the product of the immunodiffusion assay are IgG4 that is essentially free of other IgG subtypes, Laursen *et al.* does not teach or disclose the products of the claimed methods.

C. The cited art does not provide one of skill with a suggestion for modification or combination to arrive at the claimed invention.

Laursen *et al.* provide no clear and particular suggestion or motivation for its combination with Flaa *et al.* to arrive at the claimed invention. First, Laursen *et al.* do not provide any suggestion or teaching of use of a purified IgG4 subtype, or any purified IgG subtype as a therapeutic. Laursen *et al.* teach only the therapeutic use of a total IgG4 composition with subtype distribution close to that of human blood, *i.e.*, 1-3% IgG4. Second, Laursen *et al.* teach only treatment of disease or conditions that benefit from replacement or supplementation of the total IgG component of blood, and for that purpose Laursen *et al.* explicitly require a total IgG preparation with subtype distribution close to that of human blood, *i.e.*, 1-3% IgG4, for that use. See, *e.g.*, Laursen *et al.* at column 20, lines 9-15. Flaa *et al.* teach only solutions for stabilizing purified proteins and do not teach any methods for purifying proteins, including immunoglobulins. Thus, neither Laursen *et al.* nor Flaa *et al.* provide the clear and particular suggestion or motivation for their combination to arrive at the claimed invention.

In addition, Applicants respectfully remind the Examiner that there cannot be an adequate suggestion or motivation to make a proposed modification where such modification renders the prior art unsuitable for its intended purpose. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984); MPEP §2143.02. Modification of Laursen *et al.* to arrive at a purified IgG4 subtype to be "combined" with Flaa *et al.* would render the product unsuited to the use intended by Laursen *et al.* Laursen *et al.* discloses a method of purifying a total IgG preparation from other plasma proteins with the intention of using the IgG preparation to treat patients with diseases or

conditions that benefit from replacement or supplementation of the total IgG component of blood. Even if the teachings of Laursen *et al.* could be modified to arrive at a purified IgG4 preparation, as suggested by the Office Action (Laursen *et al.* specifically disclaim adjustment of plasma to pH values greater than 6.0), a purified IgG4 preparation would not be useful to treat diseases or conditions that benefit from replacement or supplementation of the total IgG component of blood. Thus, the combination of Laursen *et al.* with Flaa *et al.* found in the Office Action cannot be used as intended by the references, and cannot be assumed to provide a motivation or suggestion for their combination.

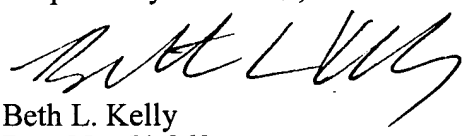
In view of the above amendments and remarks, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231

On January 31, 2002

TOWNSEND and TOWNSEND and CREW LLP

By: Joy M. Marshall

PATENT
Attorney Docket No.: 021199-000100US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: V. Ford
Pollack, William	Art Unit: 1645
Application No.: 09/660,862	DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. WILLIAM POLLACK
Filed: September 13, 2000	
For: METHOD OF MANUFACTURING IMMUNE GLOBULIN	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, William Pollack, Ph.D., being duly warned that willful false statements and the like are punishable by fine or imprisonment or both (18 U.S.C. § 1001), and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

EXHIBIT A

1. All statements herein made of my own knowledge are true, and statements made on information or belief are believed to be true and correct.

2. I am currently chairman and chief executive officer of Atopix Pharmaceuticals Corporation, the assignee of the subject application.

3. I, Dr. Pollack, graduated from the Imperial College of Science and Technology at London University with a B.Sc degree in physiology and biochemistry. I received a M.Sc degree in chemistry and physics from the St. Georges Hospital Medical School at London University and a Ph.D. in immunology and immunochemistry from Rutgers University. A copy of my curriculum vitae is attached hereto as Exhibit A.

4. I am the named and true inventor of the above-referenced patent application. I have read and am familiar with the contents of the patent application. In addition, I have read the final Office Action, dated November 2, 2001, received in the present case. It is my understanding that the Examiner believes that the Zolton *et al.* patent, U.S. Patent Number 4,597,966, anticipates the manufacturing method of the present invention. It is also my understanding that the Examiner believes that Zolton *et al.* in combination with either Cheung *et al.*, *Annals of Allergy*, Volume 50, March 1983, 155-160, Sirna, U.S. Patent No. 5,908,827, or Thomas, U.S. Patent No. 4,089,944 makes the invention of the present application obvious.

5. With this application, I claim a method of manufacturing a highly purified IgG4 immune globulin preparation. The method comprises the steps of adjusting

plasma to a pH of about 6.5 and a conductivity of between 3.5-6 millisiemens, and contacting the plasma with an anion exchange resin followed by a cation exchange resin to obtain a final effluent that comprises IgG4 essentially free of other IgG subtypes.

6. The Zolton method, unlike the method of the present application, does not result in an immunoglobulin preparation comprising IgG4 that is essentially free of other IgG subtypes. Zolton's method, instead, results in a purified stable IgG gamma globulin preparation containing all IgG subtypes including IgG1, IgG2, IgG3, and IgG4. In contrast, the present application provides a method of producing a purified IgG4 preparation free from IgG1, IgG2 and IgG3. Zolton's patent teaches a stabilized preparation of IgG (including all subtypes). The present application teaches a method of fractionating IgG into its various subtypes. It is neither suggested nor taught in the Zolton patent that the Zolton purification method results in pure IgG4 (free of all other subtypes), nor, in my opinion, could the purification system described in Zolton result in pure IgG4 free of other IgG subtypes.

7. Zolton's purification method utilizes a QAE-Sephadex anionic resin. In contrast, the present invention uses two resins, an anion exchange resin, e.g., DEAE Sepharose, followed by a cation exchange resin, e.g., CM-Sepharose. The extra fractionation step results in an IgG4 preparation free of other subtypes. Prior to the advent of the present invention, further fractionation of an IgG preparation into a purified IgG4 using chromatographic resins was not known. Again, the present invention provides a facile method of manufacturing IgG4 immune globulin that is essentially free of other IgG subtypes.

8. The purified IgG4 preparation has numerous advantages over an IgG preparation containing all of the IgG subtypes. The purer IgG4 preparation contains less protein and has a higher amount of blocking antibody per unit weight or per unit of protein that is being injected. The intravenous injection of many immune globulin products can lead to reactions that are caused by aggregation and fragmentation of the

immune globulin. The lower protein and higher blocking antibody content of the IgG4 preparation results in a preparation that is safer and more effective than the other less pure IgG preparations that contain IgG1, IgG2 and IgG3 as well as IgG4.

9. Further, the Zolton patent in view of Cheung *et al.*, or Sirna, or Thomas does not make obvious the manufacturing method of the present application, as the secondary references of Cheung *et al.*, Sirna, and Thomas do not address the deficiencies in the Zolton patent.

10. Cheung *et al.* documents a correlation between high IgG4 levels and beekeepers. This correlation, at most, indicates that there may be a role for IgG4 in the protection against anaphylactic reactions. Cheung *et al.* does not teach or suggest how to make a purified IgG4 preparation or even that a purified IgG4 preparation would be more desirable than a IgG preparation containing all of the IgG subtypes including IgG4.

11. Sirna teaches the use of ion exchange chromatography and high-resolution chromatography to extract purified polypeptide from human urine. I would not expect a purification system for the extraction of polypeptide from *human urine* to be relevant for the purification of *blood plasma* and immunoglobulins. Furthermore, the Sirna method utilizes multiple resins along with DEAE Sepharose and CM-Sepharose. Sirna does not teach or suggest the use of DEAE Sepharose and CM-Sepharose for the purification of IgG4 from human plasma.

12. Thomas teaches how to rapidly solubilize an anti-hemophilic factor composition. The Thomas reference does not teach or suggest how to make a purified IgG4 preparation. Furthermore, Thomas does not teach or suggest fractionation of IgG into an IgG4 fraction.

13. In view of the foregoing, it is my scientific opinion that, after reading the above mentioned references, the presently claimed method is novel and

unobvious over the cited art. One of skill in the art would not be motivated to make the purified IgG4 preparations using the method of the present application. Therefore, Zolton *et al.* does not anticipate this invention and Zolton *et al.* either alone or in combination with either Cheung *et al.*, Sirna, or Thomas does not make the invention of the present application obvious.

The declarant has further nothing to say.

Date: 1/28/08 By: William Pollack
William Pollack, Ph.D.

CURRICULUM VITAE
OF
DR. WILLIAM POLLACK

Education

Imperial College of Science & Technology. (London University, England). B.Sc., A.R.C.S., (Major Chemistry & Physics.)

St. Georges Hospital Medical School. (London University. England). M.Sc., (Physiology & Biochemistry). F.R.C.Path.,(Clinical Laboratory Pathology).

Rutgers - the State University of New Jersey.
Ph.D. (Immunology & Immunochemistry). Dissertation thesis: *"A study of the Factors Affecting the Zeta-Potential and Hemagglutination with Human Iso-Antibodies".*

Relevant Professional Experience

Played a leading role in the development of Ortho Diagnostic Systems from a small division into a $200M independent subsidiary company of Johnson and Johnson. Served as Vice President of Research and Development and a Member of the Board of Directors, responsible for administering a R/D budget in excess of $8M and responsible for the activities of more than 160 individuals, mostly scientists and physicians. Subsequently, at the Purdue Frederick Company, served as Vice President of R/D and Member of the Executive Committee.

Have been responsible for more than 50 new innovative products, including the first immunological pregnancy test and on which all current pregnancy test are based, the first test(s) for hepatitis and various other Human Immune Globulins including those to prevent or treat, Hepatitis, Rubella, Allergies, and Rhesus Disease of the Newborn. In addition, have had considerable manufacturing experience, including cost containment and maximizing gross profit. Also developed a new facility for the manufacture of immune globulins that was based on a novel and vastly simplified process developed under my direction.

Received the Albert and Mary Lasker Award for basic research in Antibody-Mediated-Immune Suppression and for the invention and development of an Immune Globulin to prevent Rhesus Disease of the Newborn, a product (RhoGam™) that has eradicated the disease. In addition, in recognition of this work, received numerous other awards including the John Scott Medal from the City of Philadelphia, The Karl Landsteiner Award from the American Association of Blood Banks, the Joseph Bolivar-DeLee Humanitarian Award of the City of Chicago and the Award from the New York State and the Perinatal Society for Unique Contributions to Maternal and Child Health.

Author of numerous publications, including several contributions to books and a member of many distinguished medical and scientific societies, as well as having served on the Immunological Standards Committee of the World Health Organization.

Professional History

1985-Present	Atopix Pharmaceuticals Corporation. Carlsbad, California, 92008 Chairman & C.E.O.
1981-1985	The Purdue Frederick Co. Norfolk, Conn. 06856 Vice President, R/D Member of Executive Committee.
1956-1981	Ortho Diagnostics Systems, Inc. Raritan, NJ 08869 (A Johnson & Johnson Co.) Vice President and Member of Board of Directors Director of Research.
1954-1956	Royal Columbian Hospital British Columbia, Canada. Director of Blood Band & Clinical Laboratories.
1948-1954	St. Georges Hospital Medical School, London, England
1943-1946	Royal Navy, Honorable Discharge Lieutenant(RNVR),

Academic Appointments

1974-1985	Associate Adjunct Professor. University of Medicine & Dentistry of New Jersey. (Previously Rutgers Medical School)
1968-1981	Associate Clinical Professor of Pathology College of Physicians and Surgeons Columbia University, New York City, NY.

Awards and Honors

1969	Karl Landsteiner Award of the American Association of Blood Banks.
1976	John Scott Award, Philadelphia Board of Directors of City Trusts.
1978	XXXI Annual Gibson Lecturer, Columbia Presbyterian Medical Center, New York City.
1979	Joseph Bolivar-DeLee Humanitarian Award. Chicago, Illinois.
1980	Albert and Mary Lasker Clinical Medical Research Award.
1987	Award from New York State Perinatal Society for Unique Contributions to Maternal & Child Health.
1980-2002	Listed in: Who's Who in America. Who's Who in the World. American Men and Women of Science.

Professional and Honorary Societies

American Association for the Advancement of Science

American Association of Blood Banks

American Association of Immunologists

Harvey Society

New York Academy of Medicine

New York Academy of Science

Sigma Xi

Partial Bibliography

1958 Levine, P, Stroup, M and Pollack, W., *Human Blood Groups.* In: *Bacterial and Mycotic Infections in man* by Dubos, R.J. 3rd Ed.

Pollack, W., Reiss, A.M. and Treacy, M. *Observations on the Direct Coombs Test on Cord Erythrocytes after the Addition of Complement.* Vox Sanguinis *3*: 442-448

1959 Hill, G., Pollack, W. and Levine, P. *A Critical Evaluation of a Rapid 'Broad Spectrum' Compatibility Test.* In: International Society of Blood Transfusion Proceedings of the 7th Congress, Rome, 1958, Basel; S. Karger, pp. 341-343

Pollack, W., Reiss, A.M. and Treacy, M. *The Use of Complement in the Serological Diagnosis of Hemolytic Disease of the Newborn.* In: International Society of Blood Transfusion, Proceedings of the 7th Congress, Rome, 1958. Basel; S. Karger, pp 519-522

1960 Hill, G. and Pollack, W. *Evaluation of Antibody Detection Techniques.* Int. Soc. Blood Transfusion. 8th Congress, Tokyo, 1960. Basel/New York; S.Karger, pp. 230-232

1961 Levine, P., Celano, M., Fenichel, R., Pollack, W. and Singher, H. *A "D-Like" Antigen in Rhesus Monkey, Human Rh Positive and Human Rh Negative Red Blood Cells.* J. Immunol. *87*: 747-752

1962 Pollack, W., Hager, H.J., and Hollenbeck, L.L. Jr. *The Specificity of Anti-Human Gamma Globulin Reagents.* Transfusion *2*: 17-30

1964 Freda, V.J., Gorman,J.G. and Pollack, W., *Successful Prevention of Experimental Rh Sensitization in Man with an Anti-Rh Gamma Globulin Antibody Preparation.* Transfusion *4*: 26-32

Levine, P and Pollack, W., *Hemolytic Disease of the Fetus and Newborn.* Med. Clin. of North America. *49:* 1647-1660

1965 Pollack, W., *Some Physico-Chemical Aspects of Hemagglutination.* Ann. N.Y. Acad. Science *127*: 892-900

Pollack, W., Hager, H.J., Reckel, R., Toren, D.A., and Singher, H.O. *A Study of the Forces Involved in the Second Stage of Hemmaglutination.* Transfusion. *5*: 158-153

Robertson, J.G., Freda, V.J. and Pollack. W. *Prevention of Immunization to Rh with Ant- Rh Gamma Globulin.* Fed. Proc. *24*: 696

1965 Cont' Pollack, W. and Hager, H.J., *A Physico-Chemical Study of Hemagglutination.* Basel/New York; S. Karger. 10th Cong. Int.Soc Blood Transfusion, Stockholm. 1964. pp 802-934

Gorman, J.G., Freda, V.J., Pollack, W. *Prevention of Isoimmunization to Rh Factor Using High Titer Anti-Rh Gamma Globulin.* Basel/New York; S. Karger. Proc. 10th Cong. Int. Soc. Blood Transfusion, Stockholm. 1964. pp 949-955

1966 Freda, V.J., Gorman, J.G., Pollack, W., Robertson. J.G., Jennings, E.R. and Sullivan, J.F. *Prevention of Rh Isoimmunization.* J.A.M.A. *199*: 390

Gorman, J.G., Freda, V.J., Pollack,W. and Robertson, J.G. *Protection from Immunization in Rh-Incompatible Pregnancies.* A Progress Report. Bull. New York Acad. Med. *42*: 458-473

Pollack, W. *The Zeta-Potential and Hemagglutination with Rh Antibodies.* Manual for Workshop on the Techniques Used in Antibody Identification. Am. Assoc. Blood Banks.

1967 Pollack, W. and Tripodi, D. *The role of the Immune Response in the Establishment and Rejection of Neoplastic Tissue.* Int. Arch. Allergy and Immunol. *32*: 429-436

Freda, V.J., Gorman, J.G. and Pollack, W. *Suppression of Primary Rh Immune Response with Passive Rh Immune Globulin.* N.E.J.M. *277:* 1022

1968 Pollack, W., Gorman, J.G., Freda, V.J., Jennings, E.R. and Sullivan, J.F. *Clinical Evaluation of Rh Immune Globulin in the Prophylaxis of Immunization to the Rh Factor.* Proc. 11th Cong. Int. Soc. Blood Transfusion, Sydney 1966 Bibl. Haemat. *29:* 231-236

Jennings, E.R., Dibbern, H.H., Hodell, F.H., Monroe, C., Peckham, N.H., Sullivan, J.F. and Pollack, W. *Long Beach (California) Experience with Rh Immune Globulin.* Transfusion. *8:* 146-148

Pollack,W., Singher, H.O., Gorman, J.G. and Freda, V.J. *The Prevention of Isoimmunization to the Rh Factor by Passive Immunization with Rh_0(D) Immune Globulin (Human).* Haematalogia. *2*: *No.*1: pp.1-8

Pollack, W., Gorman, J.G. and Freda, V.J. *Prevention of Rh Hemolytic Disease.* Progress in Hematology. *VII*

Pollack, W., Gorman, J.G., Freda, V.J., Ascari,W.Q. and Allen, A.E. *Results of Clinical Trials Of RhoGam™ in Women.* Transfusion. *8:* 151-153

1969 Jennings, E.R., Dibbern, H.H., Hodell, F.H., Monroe, C.H., Peckham, N.H., Sullivan, J.F. and Pollack, W. *Prevention of Rh Hemolytic Disease of the Newborn.* California Medicine, *110:*

Ascari, W.Q., Levine, P. and Pollack, W. *Incidence of Maternal Rh Immunization by ABO Compatible and Incompatible Pregnancies.* Brit. Med. J. *1*: 399-401

1970 Tripodi, D., Hollenbeck, L. and Pollack, W. *The effect of Endotoxin on the Implantation of a Mouse Sarcoma.* Int. Arch. of Allergy and Immunol. *37*: 557-585

Pollack, W. and Kochesky, R.J. *The Importance of Antibody Concentration Binding Constant and Heterogeneity in the Suppression of Immunity to the Rh Factor.* Int. Arch. Allergy and Immunol. *38:* 410-415

Pollack, W. and Reckel, R.P. *The Zeta-Potential and Hemagglutination with Rh Antibodies.* Int. Arch. of Allergy and Immunol. *38:* 417-421

1971 Tripodi, D., Weis, J., Bonness, P.E. and Pollack, W. *Identification of Platelet Orosmucoid.* Transfusion *11*: 139-144

Pollack, W., Ascari, W.Q., Kochesky, R.J., O'Connor, R.R., Ho, T. and Tripodi, D. *Studies on Rhesus Prophylaxis with Rh Positive Blood. No.1* Transfusion. *2*: 333-339

1972 Pollack, W. *Rh Immune Globulin Administered to D^u-Positive Mother: No Adverse Effect.* J.A.M.A. *221:* No. 12

Tripodi, D., Redeker, A., McKee, A.P., and Pollack, W. *Comparative Clinical Evaluation of H.A.A. Detection Among Liver Disease Patients.* Int. Arch. of Allergy and Immunol. *42:* 681-685

Tripodi, D., Gocke, D.J., McKee, A.P., Hawk, J., Campbell, J. and Pollack, W. *No.1. A comparative Clinical Evaluation of H.A.A Detection. No. 2. H.A.A Detection Among Blood Donors.* Transfusion. *12:* 109-110

1973 Levine, P., Tripodi, D., Struck, J., Zmijewski, C.M. and Pollack, W. Hemolytic Anemia Associated with Rh Null but not with Bombay Blood. Vox. Sang. Suppl. *24:* 80-83

McKee, A.P., Pollack, W. and Tripodi, D. *Low Voltage Counterimmuno-electrophoreses for the Detection of Australia Antigen.* Vox. Sang. Suppl. *24:* 80-83

1975 Freda, V.J., Gorman, J.G., Pollack, W. and Bowe, E. *Prevention of Rh Hemolytic Disease - Ten Years Clinical Experience with Rh Immune Globulin.* N.E.J.M. *293*

1975 Cont' Rancourt, M.W., McKee, A.P. and Pollack, W. *Mitochondrial Profile of a Mammalian Lymphocyte.* Ultrastructure Res. *51:* 418-424

Redeker, A.G., Moseley, J.W., Gocke, D.J., McKee, A.P. and Pollack, W. *Hepatitis B Immune Globulin as a Prophylactic Measure for Spouses Exposed to Type B Hepatitis.* N.E.J.M. *293:* 1055-1059

1976 Keith, L., Burger, G.S. and Pollack, W. *The Transfusion of Rh Negative Women.* Amer. J. Obs. Gyn. *125:* 502

Reiss, A.M. and Pollack, W. *Detection and Semiquantitation of Fetal Cells (Fetal Hemoglobin) in the Maternal Circulation.* Man. Clin Immunol.

Pollack, W. and Reckel, R.P. *A Reappraisal of the Zeta-Potential Model of Hemagglutination.* 5th Int. Convocation. Immunol., Buffalo, N.Y.17-26

1977 Ratliff, E.A., Pollack, W., Tripodi, D. and Ho, T. *Solid Phase Radioimmune Assay for Quantitating Anti-HBs in Hepatitis B Immune Globulin.* Int. Arch. of Allergy and Immunol. *4*: 231-237

Pollack, W. and Reckel, R.P. *A Reappraisal of the Forces Involved in Hemagglutination.* Int. Arch. of Allergy and Immunol. *54*: 231-237

Freda, V.J., Gorman, J.G. and Pollack, W. *Prevention of Rh Hemolytic with Rh Immune Globulin.* Am. J. Obs. Gyn. *128*: 456-460

1978 Gorman J.G., Rincon, F.J., Freda, V.J. and Pollack, W. *Closing the Utilization Gap on Rh Immune Globulin.* Med. Lab. Obs. March. p 199

Freda, V.J., Pollack, W. and Gorman, J.G. *Rh Disease: How Near the End?* Hospital Practice. June. pp 61-69

1981 Pollack, W. *Rh Hemolytic Disease of the Newborn: Its Cause and Prevention.* Reproductive Immunology *70:* 185-203

Reckel, R.P., Harris, J., Botsko, E. and Pollack, W. *A new Capillary Tube Agglutination-Inhibition Test for the Detection of Circulating Immune Complexes Containing Endogenously Bound C1q.* Immunol. Letters. *3*: 107

1982 Pollack, W. *Recent Understanding for the Mechanism by which Passively Administered Rh Antibody Suppresses the Immune Response to the Rh Antigen in Unimmunized Rh Negative Women.* Clin. Obs. and Gyn. *25*:255

1984 Pollack. W. *Mechanism of Rh Immune Suppression by Rh Immune Globulin.* 37th Annual Meeting, A.A.B.B.. San Antonio. Texas.

1985 Pollack, W. and Iny, O. *A Physico-Chemical Study of PVPI Solutions Leading to Reformulation of Betadine Preparations (5% PVPI).* J. Hosp. Infections *6:* Supplement

Gocke, D.J., Ponticas, S. and Pollack W. *In Vitro Studies of the Killing of Clinical Isolates by Povidone-Iodine Solutions.* J. Hosp. Infection *6:* 59